SunTech Medical®

OCT 20 2008

K080854

SunTech Medical, Inc.
Abbreviated 510(k) Submission
Disposable Blood Pressure Cuff
510(k) Summary
March 25, 2008

(1) Submitter information

Name:	SunTech Medical, Inc
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	SunTech Medical 507 Airport Boulevard Suite 117 Morrisville, North Carolina 27560-8200 Tel: 919-654-2332 Fax: 919-654-2301
Date prepared:	March 25, 2008

(2) Name of Device

Trade Name:	Disposable Blood Pressure Cuff
Common Name:	Blood Pressure Cuff
Classification name:	Blood Pressure Cuff, DXQ 870.1120

(3) Legally-marketed predicate devices

Sun Tech Medical has identified the CRITIKON Soft Cuff, K974080, as the predicate device for the Disposable Cuff.

The Disposable Blood Pressure Cuff is substantially equivilent to this device.

(4) Description

The device comprises tubing attached to a soft inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure. The device is connected to a non- invasive blood pressure measurement system. The device is available in the following configurations:

- 15 sizes (five neonate, ten pediatric/adult)
- Single and dual cuff tubing with connectors available for use with a wide variety of manual and automated sphygmomanometers

Pediatric			
Size	Range	Available tail length	Artwork Color
1	3-6 cm	Normal	Orange
2	4-8 cm	Normal	Turquoise
3	6-11 cm	Normal	Green
4	7-13 cm	Normal	Royal Blue
5	8-15 cm	Normal	Burgundy
Adult			
Size	Range	Available tail length	Artwork Color
Infant	8-13 cm	Normal	Orange
Child	12-19 cm	Normal and Long	Green
Sm Adult	17-25 cm	Normal and Long	Turquoise
Adult	23-33 cm	Normal and Long	Royal Blue
Lg Adult	31-40 cm	Normal and Long	Burgundy
Thigh	38-50 cm	Normal	Brown

(5) Intended Use

The Disposable Blood Pressure Cuff is intended to be used with a non- invasive blood pressure measurement system to determine blood pressure parameters on neonate, pediatric and adult patients.

(6) Comparison to Predicate Devices

The device has the same basic construction as the predicate device. Both devices are wrapped around the patients limb and secured by means of a hook and loop type fastener. The devices are manufactured from the same type of material, are available in the same size/ranges and are intended for the same patient populations.

(7) Testing and Validations

The Disposable Blood Pressure Cuff has been tested to the applicable requirements of the following standards and requirements documents. These tests have indicated passing results.

- AAMI SP10: 2002
- IEC 60601-2-30:1999
- Marketing Specification (SunTech document # 98-00162-XX-MS)

(8) Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, SunTech Medical concludes that the Disposable Blood Pressure Cuff is safe, effective and substantially equivalent to the predicate device described herein

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 20 2008

SunTech Medical, Inc
c/o Mr. Chuck Setzer
Regulatory Manager
507 Airport Blvd. Suite 117
Morrisville, NC 27560

Re: K080854
SunTech Medical Disposable Pressure Cuff, Model DC100
Regulation Number: 21 CFR 870.1120
Regulation Name: Cuff, Blood Pressure
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: October 9, 2008
Received: October 14, 2008

Dear Mr. Setzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number (if known): K080854

Device Name: Disposable Cuff

Indications for Use:

The Disposable Blood Pressure cuff is intended to be used with a non-invasive blood pressure measurement system to determine blood pressure parameters on neonate, pediatric and adult patients.

Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Richmond

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080854